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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,892	04/20/2004	Michael T. Barrett	10031033-1	7766

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EXAMINER	
SALMON, KATHERINE D	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 11/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/828,892	BARRETT ET AL.	
	Examiner	Art Unit	
	Katherine Salmon	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *10-25 and 30-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 26-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/20/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, Claims 1-9 and 26-29 in the reply filed 10/12/2006 is acknowledged.

2. The reply traverses the requirement for restriction. The reply asserts elements of the claims of Group I are found in the remaining claims of Groups II-III (p. 3 1st paragraph). The reply asserts little, if any, additional searching should be required for the claims of Groups II-III (p. 3 2nd paragraph). The reply asserts searching the groups does not impose an undue or serious burden (p. 3 3rd paragraph). This argument has been thoroughly reviewed but is not found persuasive. There is a search burden in searching all claims together. The array of group 1 could be used in a method to identify nucleic acid binding proteins therefore a search of the array of Group 1 would not necessarily overlap in scope with the search of Groups II-III. Art relating to the array would not necessarily provide descriptive information for the method for determining chromosome copy number in a cell. There is a undue burden to search both the groups because a search for only the array would not necessarily provide a descriptive search for the method.

3. Requirement for restriction is still deemed proper and is therefore FINAL.

4. Claims 10-25 and 30-33 are withdrawn from consideration as being drawn to a nonelected invention.

5. An action on the merits for Claims 1-9 and 26-29 is set forth below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Bao et al. (US Patent Application Publication 2001/0018183 August 30, 2001).

With regard to Claims 1-3 and 6, Bao et al. teaches an array comprising DNA sequences from all human telomeres and all human centromeres (p. 10 paragraph 134). With regard to Claim 4-5, Bao et al. teaches an array comprising all human telomeres and centromeres therefore, Bao et al. teaches a set of chromosome structural region oligonucleotide features for all chromosomes.

With regard to Claim 7, Bao et al. teaches an array which also comprises microdeletion syndrome regions (non-structural regions) (p. 10 paragraph 134).

With regard to Claim 8, Bao et al. teaches an array with centromeres and telomeres (structural regions) and microdeletion syndrome regions (non-structural regions) therefore the array would have at least one non-structural

region interspersed with one structural region.

With regard to Claim 9, Bao et al. teaches an array comprised of target elements of centromeres and telomeres (structural regions) and microdeletion syndrome regions (non-structural regions) (p. 10 paragraph 134). Bao et al. teaches that target elements are regions of a substrate surface that contains immobilized nucleic acids (p. 3 paragraph 45). Therefore, the nonstructural regions and the structural regions are separated on the array since each represents a spot on the array, which represents a different target element.

6. Claims 1-2, 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Pinkel et al. (US Patent Application Publication 2002/0192698 December 19, 2002).

With regard to Claim 1, Pinkel et al. teaches an array comprised of a plurality of target elements (p. 2 paragraph 13). Pinkel et al. teaches the target elements are comprised of fragments of Chromosome 20 such as centromere (structural region) (p. 2 paragraph 13 and p. 5 paragraph 56). Pinkel et al. teaches the target elements are derived from representative locations along the chromosomal region of interest (p. 5 paragraph 59). With regard to Claim 2, Pinkel et al. teaches the areas of interest are composed of different regions such as a centromere (structural region) (p. 5 paragraph 56).

With regard to Claim 7, Pinkel et al. teaches an array of fragments derived from representative locations along the chromosomal region of interest, therefore, Pinkel et al. teaches an array with both structural (centromere) and

non-structural regions (other fragments along the chromosome) (p. 5 paragraph 56).

With regard to Claims 8-9, Pinkel et al. teaches an array wherein each target is spotted onto the array at discrete positions (p. 7 paragraph 79). Because each target is place on the array in spots, the array would comprise structural regions (centromeres) at certain spots and non-structural regions at other spots therefore the two types of regions would be interspersed on the area and would be on a separate area of the area (each spot would represent a separate area).

7. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US Patent 5474796 December 12, 1995).

The claims are drawn an array comprising chromosome structural region oligonucleotide features (centromeric and/or telomeric) and non-structural region oligonucleotide features. The courts have stated that claims must be given their broadest reasonable interpretation consistent with the specification *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Ged. Cir. 1997); *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969); and *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (see MPEP 2111). The claims are given the broadest reasonable interpretation consistent with the broad claim language and specification wherein "oligonucleotide feature" is described or defined as any oligonucleotide of any size.

With regard to Claims 1-3, Brennan teaches an array which contains oligonucleotides with 10 nucleotides each (see Column 9, lines 49-50). Brennan teaches that the total array represents every possible permutation of the 10-mer oligonucleotide (see Column 9 lines 53-55). Because Brennan teaches all possible 10-mers, Brennan teaches combinations of isolated nucleic acid molecule probes that are chromosome structural region oligonucleotide features as claimed. Brennan teaches 10 mer which would comprise centromeric and telomeric sequences.

With regard to Claims 4-5, Brennan teaches an array with all possible 10 mers; therefore, the array would comprise chromosome structural region oligonucleotide features for all chromosome of a cell.

With regard to Claim 6, Brennan comprises all 10-mer sequences therefore the 10-mers of the array of Brennan would comprise oligonucleotide features of both telomeres of a chromosome. With regard to Claim 7, the 10-mer array would comprise non-structural region oligonucleotide features.

With regard to Claim 8, Brennan teaches an array with 10-mer oligonucleotides at spaced intervals on the array (column 9 lines 35-60). Therefore, Brennan teaches 10 mer fragments comprising both structural and non-structural regions interspersed on the array. With regard to claim 9, Brennan teaches that each 10 mer is attached to a position on the array (column 9, lines 35-60). Therefore, Brennan teaches an array in which the non-structural region oligonucleotide feature is on a separate part of the array from the chromosome structural region oligonucleotide feature. Each spot on the array that represents

a different 10 mer oligonucleotides would be considered a separate part of the array.

8. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Fodor et al. (US Patent 6,582,908 June 24, 2003).

With regard to Claims 1-3, Fodor et al. teaches an n-mer array comprise a solid support to which are attached all possible nucleic acid sequences of a given length (Column 17, lines 24-27). Because Fodor et al. teaches all possible 10-mers, Fodor et al. teaches both oligonucleotides from the centromeric and telomeric region of the chromosomal structure.

With regard to Claims 4-5, Fodor et al. teaches an n-mer array comprise a solid support to which are attached all possible nucleic acid sequences of a given length, therefore Fodor et al. teaches an array of a plurality of sequences of all chromosomes of a cell (Column 17, lines 24-27).

With regard to Claim 6, Fodor et al. teaches an n-mer array comprised of all 10 mer fragments. These fragments would represent chromosome structural region oligonucleotide features.

With regard to Claim 7, Fodor et al. teaches every possible 10 mer fragment on the array, therefore, these fragments would represent both structural and non-structural regions. With regard to Claim 8, Fodor et al. teaches an array of fragments of 10 mer, these fragments represent both structural and non-structural regions; therefore the array contains structural regions interspersed with non-structural regions.

With regard to Claim 9, Fodor et al. teaches an array wherein each fragment is placed on a discrete location, therefore, Fodor et al. teaches an array wherein a non-structural region is on a separate part of the array from a structural region (column 2, lines 36-40).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 26-27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bao et al. (US Patent Application Publication 2001/0018183

August 30, 2001) in view of Ahern (The Scientist July 24, 1995 Vol. 9 Issue 15 p. 20).

With regard to Claims 26-27, the recitation "for assessing chromosome copy number in a cell" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Accordingly, the claim language of "for assessing chromosome copy number in a cell" merely sets forth the intended use or purpose of the claimed kits, but does not limit the scope of the claims.

With regard to Claims 26, Bao et al. teaches an array comprising DNA sequences from all human telomeres and all human centromeres (chromosomal structural features) (p. 10 paragraph 134).

With regard to Claim 27 and 29, Bao et al. teaches labels that are applied to all nucleic acid populations such that the populations are labeled with different fluorescent markers (p. 4 paragraph 56 and p. 7 paragraph 96).

Bao et al., however, does not teach a kit.

Ahern teaches kits to deliver to researchers prepared chemicals (p. 1 last paragraph). Ahern teaches included in the kit is a sheet of instructions (Figure 1 p. 20 Hot seller, instruction sheet is in the background). With regard to the

limitation that the kits contain instructions, the inclusion of instructions is not considered to provide a patentable limitation on the claims because the instructions merely represent a statement of intended use in the form of instructions in a kit. See In re Ngai, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004)(holding that an inventor could not patent known kits by simply attaching new set of instructions to that product).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to incorporate the probes on the array of Bao et al. into a kit as taught by Ahern. The ordinary artisan would want to incorporate the probes and the array into a kit because Ahern teaches "remade biochemicals and reagents offer scientist the opportunity to better manage their time, putting these products all together in kits take the convenience one step further." (Ahern p. 24).

11. Claims 26- 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinkel et al. (US Patent Application Publication 2002/0192698 December 19, 2002) in view of Ahern (The Scientist July 24, 1995 Vol. 9 Issue 15 p. 20).

With regard to Claim 26, Pinkel et al. teaches an array comprised of a plurality of target elements (p. 2 paragraph 13). Pinkel et al. teaches the target elements are comprised of fragments of Chromosome 20 (p. 2 paragraph 13). Pinkel et al. teaches the target elements are derived from representative locations along the chromosomal region of interest (p. 5 paragraph 59).

With regard to Claim 27, Pinkel et al. teaches labeling reagents for target elements (samples) (p. 4 paragraph 42). With regard to Claim 28, Pinkel et al. teaches PCR primers for adding modified nucleotides to the target samples (centromere) (p. 6 paragraph 63). With regard to Claim 29, Pinkel et al. teaches labeling regents, which can be used to differentially label two sample populations on the array (p. 5 paragraph 59 and p. 4 paragraphs 43-44).

Pinkel et al., however, does not teach a kit.

Ahern teaches kits to deliver to researchers prepared chemicals (p. 1 last paragraph). Ahern teaches included in the kit is a sheet of instructions (Figure 1 p. 20 Hot seller, instruction sheet is in the background). With regard to the limitation that the kits contain instructions, the inclusion of instructions is not considered to provide a patentable limitation on the claims because the instructions merely represent a statement of intended use in the form of instructions in a kit. See In re Ngai, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004)(holding that an inventor could not patent known kits by simply attaching new set of instructions to that product).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to incorporate the probes on the array of Pinkel et al. into a kit as taught by Ahern. The ordinary artisan would want to incorporate the probes and the array into a kit because Ahern teaches "remade biochemicals and reagents offer scientist the opportunity to better manage their time, putting these products all together in kits take the convenience one step further." (Ahern p. 24).

12. Claims 26-27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan (US Patent 5474796 December 12, 1995) in view of Ahern (The Scientist July 24, 1995 Vol. 9 Issue 15 p. 20).

With regard to Claims 26, Brennan teaches an array which contains oligonucleotides with 10 nucleotides each (see Column 9, lines 49-50). Brennan teaches that the total array represents every possible permutation of the 10-mer oligonucleotide (see Column 9 lines 53-55). Because Brennan teaches all possible 10-mers, Brennan teaches combinations of isolated nucleic acid molecule probes that are chromosome structural region oligonucleotide features as claimed. Brennan teaches 10 mer which would comprise centromeric and telomeric sequences.

With regard to Claim 27, Brennan teaches P^{32} (a labeling reagent) to label the probes on an array (Column 9 lines 59-60). With regard to Claim 29, Brennan teaches P^{32} (a labeling reagent) to label the probes (all 10 mers so therefore at least two chromosomal samples) on an array, which would distinguish the probes.

Brennan, however, does not teach a kit.

Ahern teaches kits to deliver to researchers prepared chemicals (p. 1 last paragraph). Ahern teaches included in the kit is a sheet of instructions (Figure 1 p. 20 Hot seller, instruction sheet is in the background). With regard to the limitation that the kits contain instructions, the inclusion of instructions is not considered to provide a patentable limitation on the claims because the

instructions merely represent a statement of intended use in the form of instructions in a kit. See In re Ngai, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004)(holding that an inventor could not patent known kits by simply attaching new set of instructions to that product).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made incorporate the probes on the array of Brennan into a kit as taught by Ahern. The ordinary artisan would want to incorporate the probes and the array into a kit because Ahern teaches "remade biochemicals and reagents offer scientist the opportunity to better manage their time, putting these products all together in kits take the convenience one step further." (Ahern p. 24).

13. Claims 26-27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fodor et al. (US Patent 6,582,908 June 24, 2003) in view of Ahern (The Scientist July 24, 1995 Vol. 9 Issue 15 p. 20).

With regard to Claims 26, Fodor et al. teaches an n-mer array comprise a solid support to which are attached all possible nucleic acid sequences of a given length (Column 17, lines 24-27). Because Fodor et al. teaches all possible 10-mers, Fodor et al. teaches both oligonucleotides from the centromeric and telomeric region of the chromosomal structure.

With regard to Claim 27, Fodor et al. teaches labeling reagents for the samples on the array (Column 7 lines 19-25). With regard to Claim 29, Fodor

et al. teaches labeling reagent to label the probes (all 10 mers so therefore at least two chromosomal samples) on an array, which would distinguish the probes.

Fodor et al., however, does not teach a kit.

Ahern teaches kits to deliver to researchers prepared chemicals (p. 1 last paragraph). Ahern teaches included in the kit is a sheet of instructions (Figure 1 p. 20 Hot seller, instruction sheet is in the background). With regard to the limitation that the kits contain instructions, the inclusion of instructions is not considered to provide a patentable limitation on the claims because the instructions merely represent a statement of intended use in the form of instructions in a kit. See In re Ngai, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004)(holding that an inventor could not patent known kits by simply attaching new set of instructions to that product).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to incorporate the probes on the array of Fodor et al. into a kit as taught by Ahern. The ordinary artisan would want to incorporate the probes and the array into a kit because Ahern teaches "remade biochemicals and reagents offer scientist the opportunity to better manage their time, putting these products all together in kits take the convenience one step further." (Ahern p. 24).

Conclusion

14. No Claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Salmon
Examiner
Art Unit 1634

BJ FORMAN, PH.D.
PRIMARY EXAMINER